HAIRMAX.com

Advanced 7

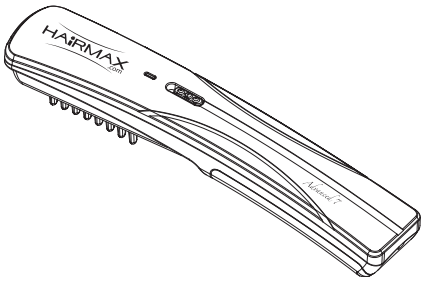
USER MANUAL

HairMax Advanced 7

The HairMax LaserComb has helped hundreds of thousands of people-combat their hair loss and grow beautiful hair. Now, Lexington is proud to introduce the next generation of the revolutionary HairMax LaserComb®.

Introducing the New HairMax Advanced 7

Using advanced laser technology, the Advanced 7 provides safe and nourishing laser light energy to weakened hair follicles. The laser light energy stimulates the hair follicle, promoting new hair regrowth and producing healthier, more beautiful hair. The new Advanced 7 provides safe and effective at home treatment as the original HairMax, but now it is cordless. The new Advanced 7 features a sleek ergonomic design powered by four AA batteries. Now that the HairMax is battery powered, it gives you the freedom of movement as you treat your thinning hair.



The new HairMax Advanced 7 utilizes Lexington's patented hair parting teeth mechanism. Remember, the laser treatments are only effective when the laser reaches the scalp. The teeth of the HairMax part the hair, moving it aside, allowing the maximum amount of laser energy to reach the scalp and energize the weakened hair follicles. Like brushing your teeth to maintain healthy teeth & gums, regular HairMax usage is recommended. Use the HairMax three times a week on non-consecutive days for about 15 minutes a session. Over the first few months, you may notice a gradual increase in the number of hairs in a specific location. Most users realize on-going improvements as they continue to use the HairMax. If you stop treating your scalp with the HairMax, your hair may regress back to its previous state.

ABOUT LEXINGTON INTERNATIONAL

Lexington International, LLC is a leader in hair growth, hair care and hair science. The technology behind the HairMax LaserComb is a result of 20+ years of Research & Development in Sydney, Australia and the USA. Our primary objective is to help those suffering from Androgenetic Alopecia. The goal is to provide an effective treatment that is affordable, easy to use and provides noticeable results without adverse side effects. Lexington bases its success on the number of people whose lives are enriched by our products. We truly care about conducting our business ethically and appropriately. Because of this, Lexington complies with the FDA's Good Manufacturing Practices, is ISO 9001 & 13485 certified in quality standards and our products meet CE requirements for electrical and laser safety. Lexington's products are also Patented and Trademarked across the world.

BENEFITS

The HairMax LaserComb is a home-use Low-Level Laser PhotoTherapy device to treat hair loss (Androgenetic Alopecia) and promote hair growth. The Laser PhotoTherapy process bathes the hair and scalp in laser light to energize weakened hair follicles. In addition to new hair growth and reduction in shedding, many users also routinely report normalization of scalp conditions, increased body, shine and manageability of their hair. Individual results may vary, but over time, most users continue to see an improvement of their hair and scalp conditions. If you stop using the HairMax your hair may regress back to its original state.

More reasons why HairMax users are satisfied with HairMax:

- Real Results within just weeks
- Thicker, Fuller, Healthier Hair
- Improved Hair Condition
- Convenient Home Treatment
- Certified, Completely Safe
- High User satisfaction

CLINICAL DATA

The results of the key clinical study performed with the HairMax LaserComb led to US FDA Clearance to market in January 2007. This was considered a landmark event in the treatment of Androgenetic Alopecia. These clinical results were published in *Peer Reviewed Journal* "HairMax LaserComb Phototherapy Device in the Treatment of Male Androgenetic Alopecia*".

Study Objectives

The study was conducted to support the FDA 510(k) submission and was subjected to an Investigational Review Board (IRB) approval and conducted in accordance with GCP (Good Clinical Practices). The objectives of the study were to assess the following:

- Promotion of hair growth through changes in hair density
- Cessation of hair loss
- Overall scalp health
- Safety

Study Design

The study was designed as a multi-centered, double- blinded, randomized sham-device controlled trial conducted at four sites in the United States. Subjects were instructed to use the laser hair growth treatment device three times per week on non-consecutive days, for a total of 26 weeks. Hair density measurements were performed at baseline, immediately prior to randomization and again at 26 weeks.

Subject Population and Demographics

The study population included males between the ages of 30 and 60 years with a diagnosis of Androgenetic Alopecia who had been experiencing active hair loss within the last 12 months. The inclusion criteria required a Norwood-Hamilton Classification of IIa to V and Fitzpatrick Skin Type Classification of I to IV.

Clinical Results

Subjects in the HairMax LaserComb® laser hair treatment group had significantly greater increase in mean terminal hair density than subjects in the sham group ($p<0.0001$). Subjects in the HairMax LaserComb® group also had significantly better subjective assessments of overall hair growth than subjects in the sham group ($p=0.010$). No subject experienced a serious adverse event from the laser hair loss treatment and the adverse event profiles were similar between the two treatment groups.

*Clin Drug Invest 2009: 29 (5): 283-292

WARNINGS AND PRECAUTIONS

WARNING: Only use the HairMax according to the instructions provided. Any other use is not recommended.

WARNING: Basic safety precautions should be observed when using this, or any other electrical device. Do not allow children to use or play with the HairMax. Keep out of reach of children. It is not a toy.

WARNING: Laser Light - Avoid Direct Eye Exposure. Do not point laser or allow laser light to be directed or reflected toward other people. Never use magnifying optical instruments with the HairMax. Do not stare directly at the laser light or its reflection off a mirror-like surface. Doing so can cause temporary irritation to your eyes. Prolonged direct exposure can harm your eyes.

CAUTION: If you are taking any photosensitizing medications or receiving any therapy that sensitizes the skin to light, use caution when using the HairMax. Please consult your physician if you have any other concerns.

CAUTION: Never use acetone or other solvents on any part of the HairMax. Use of solvents on the window can block the laser light from coming through.

CAUTION: Never use the HairMax if the cord or plug is damaged. Do not put strain on the cord. If any malfunction occurs, do not attempt to repair the HairMax yourself. This appliance has no user-serviceable parts and is not to be opened or modified by the user. Use the HairMax only for its intended use as described in this manual. Contact Lexington International LLC for repairs at 561.417.0200.

The following laser safety label can be found on this product:

Laser Aperture
LASER LIGHT
AVOID DIRECT EYE EXPOSURE
CLASS 3R LASER PRODUCT
650nm, <5mW CW
CLASSIFIED PER IEC 60825-1,
Ed 2, 2007-03
Complies with FDA performance standards for laser products except for deviations pursuant to Laser Notice No. 50, dated June 24, 2007
6VDC ⎓ @.55 amps power supply
Manufactured By:
Lexington International LLC
2901 Clint Moore Road #260
Boca Raton, FL 33496 USA
Model: HM1 V6.02
Serial No:
CE

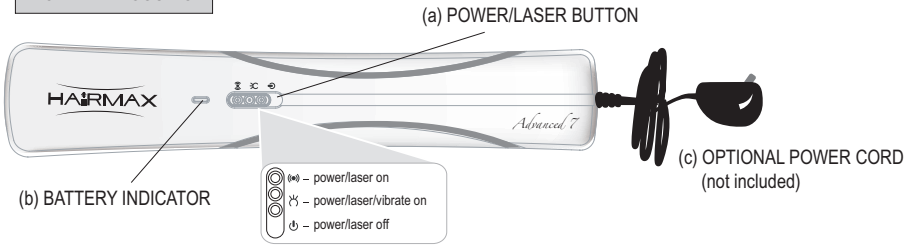
Wavelength: 655 nm
visible red light
This Laser Product is designated as Class 3R during all procedures of operation.
Note: HairMax LaserComb has no user-serviceable parts.
Location: On the underside of the handle
Model version 7-VI

Accessible Laser Parameters	Wavelength 655 nm Laser Power for classification <5mW CW Beam Diameter <5 mm Divergence 57 mrad Number of lasers 7

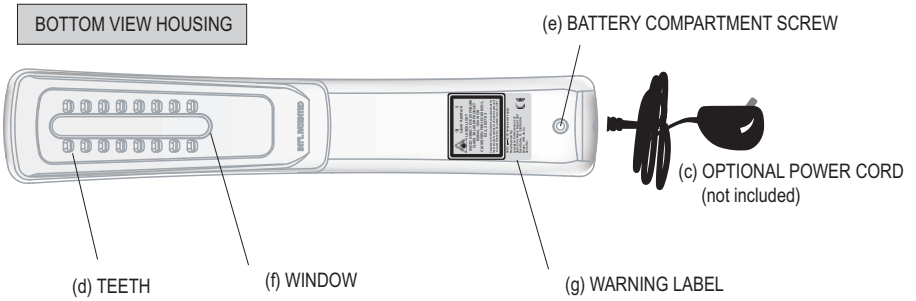
Please visit http://www.internationalhairmax.com/QualitySafety for more information or call 561.417.0200

HAIRMAX Advanced 7 - PARTS

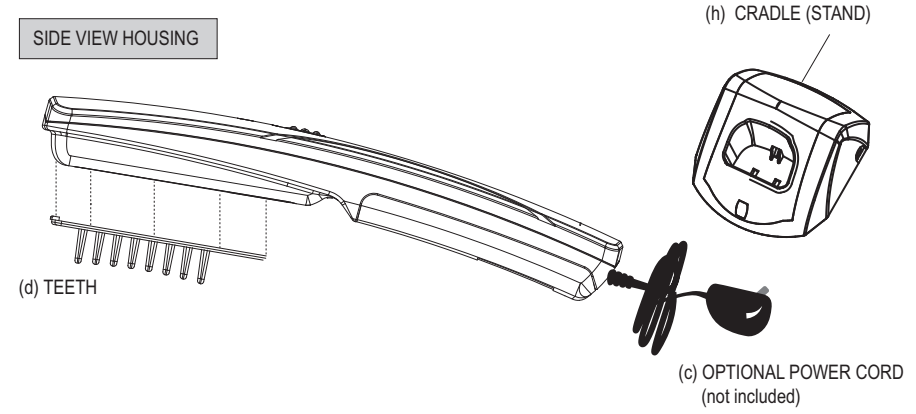
TOP VIEW HOUSING



BOTTOM VIEW HOUSING



SIDE VIEW HOUSING

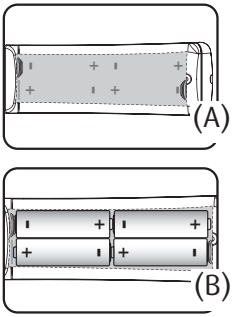


PARTS:
(a) POWER/LASER BUTTON to turn on/off the device.
(b) BATTERY INDICATOR green when batteries are fully charged, flashing red when batteries need replacement.
(c) POWER CORD optional, not included.
(d) TEETH removable for cleaning.
(e) BATTERY COMPARTMENT SCREW remove when replacing batteries.
(f) LASER WINDOW do not look ito laser window when laser is turned on. See CAUTIONS.
(g) WARNING LABEL - contains SERIAL NUMBER - not removable.
(h) CRADLE/STAND optional, not included.

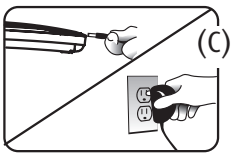
REPLACING THE BATTERIES

The Advanced 7 is powered by four(4) AA batteries. Use the following steps to replace the batteries:

1. Using an ordinary Phillips screwdriver, remove the battery compartment screw. See Graphic (e) on Page 6. The screw will remain attached to the housing.
2. Gently lift battery compartment cover (A)
3. Insert batteries. Be sure to align batteries as shown on bottom of battery compartment (B).
4. Replace cover. Tighten screw.



The HairMax Advanced 7 is designed to provide the optimum laser output even as the batteries age. When the batteries weaken to the point where they will no longer power the lasers to their optimum power level, the green BATTERY INDICATOR (b) will flash from green to red and the lasers will flash. This is an indication that the batteries need to be replaced. Please follow the instructions above to replace the batteries.



In addition, the Advanced 7 can be powered directly by the optional POWER CORD. Plug the power cord into the end of the Advanced 7. Plug the other end into a electrical outlet. See graphic (C).

PROPER USAGE

The HairMax is a very effective product if used correctly. The HairMax is manufactured using precision components and should provide years of trouble-free service under normal usage. Please take time to read this entire instruction manual before operating the HairMax.

Use the HairMax 3 times per week on non-consecutive days. (For example, Monday, Wednesday, and Friday). The total time of each treatment should be 15 minutes. More frequent or longer usage will not increase results. Maximum results will not be seen if you do not follow the recommended treatment schedule.

Like brushing your teeth to maintain healthy teeth and gums, using the HairMax as recommended is needed to maintain healthy hair. If you stop using the HairMax, your hair may regress back to its original state.

Studies conducted during 20 years of development of the HairMax indicate that there is a maximum rate of return. Lexington has determined that using the HairMax for about 15 minutes three times a week will provide the best results.

While there are no negative side effects from overuse, the best results are consistently obtained by using the HairMax according to directions. It is recommended that the HairMax be used on a clean scalp after washing. Your hair can be wet, towel dried or dry. If you do not shampoo every day, still use the HairMax as directed but check to make sure the laser window is clean. The HairMax should be used before applying any other topical treatments, gels, sprays or concealing products.

INSTRUCTIONS FOR USE

HairMax Advanced 7 can function by either using the batteries or directly from the optional power cord. (please refer to REPLACING THE BATTERIES on page 7.)

GETTING STARTED

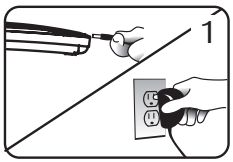
1. Read and follow all directions prior to use.

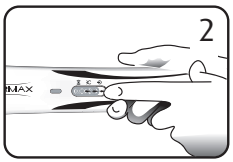
2. If you're using POWER CORD (optional-not included), place one end directly into the handle end of the HairMax and the other end into an indoor electrical outlet (Illustr. 1).

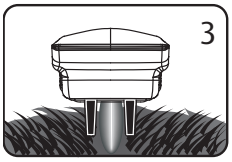
3. Slide the POWER/LASER BUTTON to the middle or top position.(Illustr. 2). (Middle position activates the laser and vibrate feature. Top position is laser only). You can clearly see the laser light when the HairMax is operating. (Avoid Direct Eye Exposure when the laser is illuminated.) The HairMax is now ready for use.

   Note: The HairMax will automatically vibrate every four (4) seconds. This is an indication for the user to move the HairMax to the next portion of the scalp. For turning off vibration function please refer to page 10.

4. Place the HairMax flat on your scalp making sure that both rows of teeth are touching the scalp (Illustr. 3).

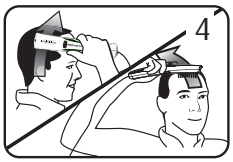


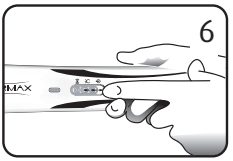




5. Start at your hairline. Move the HairMax slowly (in combing motion) by placing the device on a spot and leaving it there for 4 seconds. Once you feel the vibration move the HairMax about 1/2 inch (1 cm) to the next spot without lifting the device off your head. You will make a few complete passes over your scalp. For the first pass, move the HairMax against the direction of the hair growth - front to back (Illustr. 4) and side to side on the second pass (Illustr. 5). Repeat these passes within the recommended 15 minutes.

IMPORTANT: Do not lift the HairMax off of the head when moving every 4 seconds. The HairMax features a pair of comb teeth that part the hair so the light can more effectively penetrate to the scalp.





6. If you have long hair, use an ordinary comb or your hand to lift the long hair out of the way allowing the HairMax to deliver the laser light to the scalp (Illustr. 5)

7. Turn off the HairMax by sliding the POWER/LASER BUTTON to the lowest position. If using the optional power cord, remove the POWER CORD from wall electrical outlet and return the device to the CRADLE/STAND for storage. (Illustr. 6)

VIBRATION TIMER

The HairMax is most effective when used correctly. In order to help time the movements, the HairMax will automatically vibrate every 4 seconds.

The vibration can be turned off by sliding the POWER/LASER BUTTON to the uppermost top position.

Please Note:
It is important to move the HairMax very slowly. Remember, you are bathing the scalp with laser light. If you move it too fast, the treatment will not be as effective.

MAINTENANCE INSTRUCTIONS

Always unplug the HairMax from the power electrical outlet before cleaning.

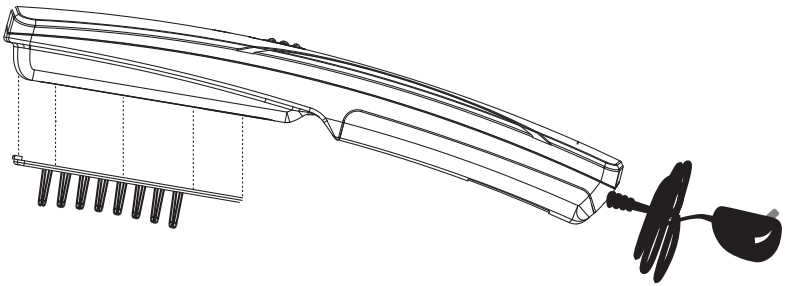
DO NOT use acetone or any other solvents on any part of the HairMax. Use of acetone or other solvents to clean the window can immediately block most of the laser light from coming through.

To clean the LASER WINDOW (from where the laser light shines through), unplug the device, turn power off and gently clean with a soft, slightly moistened cloth. Do not use any soaps or detergents – just warm water.

Cleaning comb TEETH

To keep the TEETH of the combs clean, gently remove any hairs or dust with a slightly moistened towel.

For a more thorough cleaning, gently pull out comb TEETH from the center. TEETH can be washed using soap and water. Dry combs thoroughly and replace them by inserting the top of the TEETH first. Then, press the bottom of the TEETH with your thumb until they click into place. To order replacement combs, please order online at www.hairmax.com or contact Lexington International at 561.417.0200.



If the POWER CORD becomes twisted, unplug and straighten it prior to use. Do not put strain on POWER CORD if you need to untangle or straighten it.
Only use directions, cleaning methods and operating procedures as specified in this manual.

WARRANTY

The HairMax Advanced 7 is warranted by Lexington International LLC ("Manufacturer") against defects in materials or workmanship for 24 months from date of purchase. If this product is determined to be defective, Lexington will repair or replace it, at its option, at no charge during the warranty period.

After the warranty period, the user must pay for all parts and labor charges. If the product is repaired or replaced, either within or outside the warranty period, Lexington reserves the right to provide equivalent parts in different colors to your original product.

This warranty does not cover damages caused by acts of God, misuse, negligence, accident, modification of, or to any part of the product. This warranty does not cover damage due to improper operation or maintenance, connection to improper voltage supply, or attempted repair by anyone other than Lexington. This warranty is void if product is tampered with.

To obtain warranty service, you must deliver the product freight prepaid, in either its original packaging or packaging affording an equal degree of protection, together with your name and address, to:

Lexington International LLC
2901 Clint Moore Rd, Suite 260
Boca Raton, FL 33496, USA

Limitation of Liability; Indemnity: Except as expressly set forth above, Lexington International LLC shall not be liable for any special, indirect, or consequential damages that are directly or indirectly related to the use of, or the inability to use, the HairMax, even if Lexington International LLC has been advised of the possibility of such damages whether in an action of contract, negligence or other tortuous action. Some states do not allow the exclusion or limitation of incidental or consequential damages, so the above limitation or exclusion may not apply to you.

Governing Law: The usage of the HairMax and the interpretation of its terms shall be governed by and construed in accordance with the laws of the State of Florida applicable to agreements negotiated, executed and performed wholly and solely within the State of Florida. The parties agree that the State of Florida's conflicts of laws rules shall not apply to this Agreement or any transaction performed by or under this Agreement.

Jurisdiction and Venue: The parties irrevocably submit and consent to the sole and exclusive jurisdiction and venue of the Florida state courts in and for Palm Beach County, Florida, U.S.A. and the Federal Courts in and for the Southern District of Florida, U.S.A. The parties agree not to raise the defense of forum non conveniens.

Authorized Representative in Europe (Regulatory Affairs Only): Emergo Europe, Molenstraat 15, 2513 BH The Hague, The Netherlands. Tel: (31) (0) 70 345-8570 Fax: (31) (0) 70-345-7299

Congratulations on becoming a HairMax user!

To validate your warranty please register online at www.internationalhairmax.com/warranty or call 561.417.0200

⚠ ELECTRICAL SAFETY

To reduce the risk of hazard by electric shock:

- Always unplug the HairMax from the power outlet immediately after use.
- Do not use while near water or while bathing.
- Do not place or store the HairMax where it can fall or be pulled into a tub or sink.
- Do not expose the HairMax to running water, or drop into water or any other liquid. If the HairMax falls into water, unplug it immediately from the power outlet.
- Do NOT reach into or touch the water.
- If using the HairMax near water, the use of an electrical outlet protected by a Ground Fault Circuit Interrupter is recommended.
- Do not use the HairMax near heated surfaces. Contacting a heated surface with the cord or plug can cause the product to malfunction and produce an electrical shock.

RISKS

Harm to Eyes - Do not shine the light from the HairMax directly into your eyes for extended periods of time. Prolonged direct exposure to your eyes may cause harm to your eyes.

Scalp Itching - If you experience more than mild itching during usage of the HairMax, please consult a physician.

Tingling - If you feel a more than a mild and temporary tingling lasting for a short period of time after applying HairMax, please consult a physician.

How to Monitor Device Activity

Your HairMax is inspected and tested during production. When working properly, the BATTERY INDICATOR light will illuminate green and red laser light will be visible coming from the laser window. DO NOT look directly at the laser light.

Shine the laser light at the palm of your hand to see red laser light "speckles" appear. You will also feel a vibration every 4 seconds to help time the treatment.

Do not operate the laser if the unit is defective or damaged. If the laser light does not appear, or there is no vibrate, contact Lexington International LLC for repair or replacement.

Device Failure Mode

The laser light does not fade or diminish over time. At the end of the laser's life or if it fails for any other reason no red light will shine out of the device. Do not look directly at the laser light. Direct the laser light at the palm of your hand to see red laser light "speckles" appear. If no light appears, contact Lexington International LLC for repair or replacement.

Expected Life of the HairMax

The HairMax is a Low-Level Laser Therapy device manufactured under strict quality controls and validation through GMP (Good Manufacturing Practices). The HairMax contains a high quality laser diode designed to last at least 15,000 hours. Based on that rating and the durability of the components being used, all models of the HairMax will provide you with many years of reliable service.

TROUBLESHOOTING

Before sending your HairMax in for repair, please try these helpful items. If these do not resolve your problem, please contact Lexington's warranty department.

My HairMax will not turn on

- Make sure your HairMax has fresh batteries or it is plugged into the power cord.
- Insert power cord into the HairMax. Slide the POWER/LASER BUTTON to the on position.
- Try another wall electrical outlet.

My HairMax is turning off during use

- Make sure your HairMax has fresh batteries or plugged into power cord.
- Insert power cord into the HairMax. Slide the POWER/LASER BUTTON to the on position
- Try another wall electrical outlet.

My HairMax will not turn off.

- Slide the POWWER SWITCH to the lowest OFF position.
- If using power cord, unplug HairMax

My HairMax vibrates irregularly or doesn't vibrate at all

- Make sure the POWER SWITCH is in the middle position.

My HairMax vibrates, but I do not see the laser

- Make sure your HairMax has fresh batteries or plugged into power cord.

If these helpful tips did not resolve your problem,
please contact Lexington Intl. LLC for repair or replacement:

Lexington International, LLC
777 Yamato Road, Suite 105
Boca Raton, FL 33431
Tel. 561.314.2430
info@hairmax.com
www.internationalhairmax.com

Warranty Card

The HairMax has a 2 year warranty against defects in materials or workmanship from Lexington International, LLC. Items that are damaged or abused are not covered under the warranty and will be charged at their regular repair rates. Lexington may extend this warranty period under certain product failures. Please refer to the User Manual for complete warranty terms. We guarantee your satisfaction.

To validate your warranty please return this completed warranty card or register online at: www.internationalhairmax.com/warranty

Name:_____

Serial Number:_____

Date of Purchase:_____

Address:_____

_____

City:_____**State:**_____

ZIP/Postal Code:_____ **Country:**_____

Email:_____

Where did you purchase this product (Reseller Name)?

_____

What factors influenced your purchase of this product?

_____

_____

_____

*Please fill out this form, fold it, staple or tape it at the designated area, place postage stamp and mail it back to us.

tape
or staple

HAIRMAX
.com

Place
Stamp
Here

Lexington International, LLC
2901 Clint Moore Rd., #260
Boca Raton, FL 33496
USA

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Advanced 7

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www.internationalhairmax.com/warranty

www.InternationalHairMax.com

Patented in the USA. Patent Pending in 104 countries.
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